

K963474
Jan. 22, 1997

**DeRoyal Industries, Inc.
Tuxedo Vest Restraint**

510(k) Summary

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED**

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc.
ADDRESS: 200 DeBusk Lane
Powell, TN 37849

TELEPHONE: (423) 938-7828
CONTACT: Camille Matlock
DATE OF PREPARATION: August 30, 1996

DEVICE NAMES

NAME: DeRoyal Industries, Inc. Tuxedo Vest Restraint
COMMON/USUAL NAME: Tuxedo Vest Restraint
CLASSIFICATION NAME (if known): Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETING DEVICES

J.T. Posey Company
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Tuxedo Vest Restraint is a protective restraint device that is intended for medical purposes to limit movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Tuxedo Vest Restraint is designed similar to those marketed by other manufacturers. The Tuxedo Restraint is primarily comprised of white or plaid tietex with polyester straps. The fasteners are made of a nylon hook and loop or plastic.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Tuxedo Vest Restraint is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit movements thereby enabling examination or protection of the patient or others. The Tuxedo Vest Restraint is a protective restraint that is intended to be used with a bed or wheelchair.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of plaid or white tietex and polyester straps. Fasteners are made of hook and loop or plastic.	Same
Size	X-Small, Small, Medium, Large, X-Large, XX-Large, XXX-Large	Same
Vehicles for Attachment	Bed or Wheelchair	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Moderately agitated or disoriented Prone to sliding Actively trying to get out of bed or wheelchair	Same